IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	09/476,485	Art Unit:	1644
Applicant(s):	Colucci et al.	Examiner:	M. Belyavskyi
Date Filed:	December 30, 1999	Conf. No.:	7906
Docket No.:	PHY-003US1/108236.119	Cust. No.:	23483
Title:	**Progenitor Cell Preservation Factors and Methods for and Products of Their Use**		

CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being transmitted via facsimile on the date indicated below to Examiners Tony Caputa and Christina Chan at the United States Patent and Trademark Office at (571) 273-0829 and (571) 273-0841 respectively.

11-22-04
Date of Transmission

Melissa Diaz

COMMUNICATION IN RESPONSE TO TELEPHONIC EXAMINER INQUIRY

In response to the telephonic message from Examiners Tony Caputa and Christina Chan on November 8, 2004, regarding the relationship of the amino acid sequences listed in Figures 2 and 24B to the sequences recited in the pending claims (attached herewith as **Exhibit A**), Applicants provide the following remarks.

Figure 2 (attached herewith as **Exhibit B**) provides a direct amino acid sequence comparison of the β and α subunits of the mannose lectin described by Gowda *et al.* (*J. Biol. Chem.* 269:18789-18793, 1994; SEQ ID NO:49 and SEQ ID NO:51) and the amino acid sequence of the β and α subunits of Dl-FRIL, a representative, non-limiting FRIL family member of the invention (SEQ ID NO:50 and SEQ ID NO:52). The combination of the 105 amino acid sequence of the β subunit (SEQ ID NO:49) and the 132 amino acid sequence of the α subunit (SEQ ID NO:51) provides the 237 amino acid sequence of the Gowda mannose lectin (SEQ ID NO:55). Similarly, the combination of the 123 amino acid sequence of the β subunit (SEQ ID NO:50) and

the 141 amino acid sequence of the α subunit (SEQ ID NO:52; excluding the six amino acids following the stop codon) provides the 264 amino acid sequence of a D1-FRIL of the present invention (SEQ ID NO:2; **Exhibit C**).

Figure 24B (attached herewith as **Exhibit D**) provides a direct amino acid sequence comparison of the mannose lectin described by Gowda *et al.* (SEQ ID NO:55) and the amino acid sequences of Pv-FRIL, a representative, non-limiting FRIL family member of the invention (SEQ ID NO:56), and a PHA-E lectin (SEQ ID NO:57). Note that the amino acid sequence of a Pv-FRIL shown in this figure (SEQ ID NO:56) is identical to SEQ ID NO:6 (**Exhibit E**), as recited in the claims (except for the omission of 24 amino acids of SEQ ID NO:6 following the stop codon).

Accordingly, the combination of Figures 2 and 24B provide an amino acid sequence comparison of a D1-FRIL and a Pv-FRIL of the invention with Gowda's mannose lectin. Moreover, both Figures 2 and 24B indicate identically conserved residues (by bars in Figure 2 and boxes in Figure 24B).

Furthermore, the specification provides significant guidance for

(i) determining the amino acid sequence identity between two proteins (specification, page 20, line 11 to page 21, line 13, **Exhibit F**);

(ii) making conservative amino acid substitutions (specification, page 29, lines 12-24, **Exhibit G**); and

(iii) performing site-directed mutagenesis (specification, page 33, lines 3-7, and page 57, line 20 to page 58, line 24, **Exhibit H**).

Applicants note that the Federal Circuit has made clear that a patent need not teach, and preferably omits, what is well known in the art (*see, In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991)). Based on the knowledge available to one of ordinary skill in the art at the time of the filing of the instant application, and further based on the disclosure in the instant specification (*see*, above), Applicants respectfully assert that one of ordinary skill in the art could have readily created an alignment of D1-FRIL, Pv-FRIL and Yam-FRIL (**Exhibit I**). To assist the Examiner, such an alignment is provided herewith as **Exhibit J**.

Based upon the sequence alignments, one of ordinary skill in the art would be readily able to (i) identify conserved and non-conserved regions in the FRIL proteins; (ii) make amino acid substitutions using methods well known in the art; and (iii) test the mutated FRIL proteins for their ability to bind a normally glycosylated FLT3 receptor (*see*, Example 2 of the application), preserve hematopoietic progenitor cells and/or reduce a progenitor cell depleting activity in a subject undergoing therapeutic treatment having progenitor cell depleting activity(*see*, Examples 6 and 7 of the application).

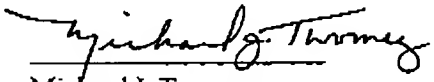
Therefore, Applicants respectfully contend that the pending claims are fully enabled by the specification. Accordingly, Applicants request that the rejection under 35 U.S.C. § 112, first paragraph (enablement) be reconsidered and withdrawn.

No fees are required with the instant filing. However, in the event that any additional fees are required to maintain the pendency of this application, the Commissioner is hereby authorized to charge any such fees, or to credit any overpayments, to Attorney Deposit Account No. 08-0219.

Respectfully submitted,

WILMER CUTLER PICKERING HALE AND DORR LLP

Date: November 22, 2004



Michael J. Twomey
Reg. No. 38,349
Attorney for Applicants

WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel: (617) 526-6190
Fax: (617) 526-5000

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12/6/04
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Rochelle Capobianco
Rochelle Capobianco

Dear Sir:

Attached for the file of the above-referenced application is a copy of a communication sent via facsimile to Quality Assurance Specialist, Tony Caputa, and Supervisory Patent Examiner, Christina Chan, on November 22, 2004, in response to a telephonic request for information from them regarding the application.

No fees are believed to be due with the instant communication. However, in the event that any additional fees are required to maintain the pendency of this application, the Commissioner is hereby authorized to charge any such fees, or credit any overpayments, to Deposit Account No. 08-0219.

Respectfully submitted,

WILMER CUTLER PICKERING
HALE AND DORR LLP

Date: December 6, 2004

Michael J. Twomey
Reg. No. 38,349
Attorney for the Applicants

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Re: U.S. Patent Application No. 09/476,485 filed 12/30/1999
Title: Progenitor Cell Preservation Factors and Methods for and Products of Their Use
First Inventor: Colucci, et al.
Examiner: M. Belyavskyi Group Art Unit: 1644
Attorney Docket No.: PHY-003US1/108236.119

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